



Docket No. 68811-A/JPW/GJG/NDP

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Sharon Cohen-Vered, et al.

Serial No. : 10/758,397

Filed : January 14, 2004

FOR : PARENTERAL FORMULATIONS OF PEPTIDES FOR THE

TREATMENT OF SYSTEMIC LUPUS ERYTHEMATOSUS

1185 Avenue of the Americas New York, New York 10036

October 13, 2004

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

Sir:

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

In accordance with their duty of disclosure under 37 C.F.R. §1.56, applicants would like to direct the Examiner's attention to the following documents which are listed on Form PTO-1449 (Exhibit A) and are also listed below. A copy of the references listed below as items 1-7 are attached hereto as Exhibit 1-7.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b)(3) before the mailing of a first Office Action on the merits. Thus, this Information Disclosure Statement should be entered and considered.

PCT International Application Publication No. WO 99/31066
 published June 24, 1999 (Exhibit 1);

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- 2. Brosch N. et al. (2000) A Peptide Based on the Sequence of the CDR3 of a Murine Anti-DNA mAb is a Better Modulator of Experimental SLE than its Single Amino Acid-Substituted Analogs. Cellular Immunology, 205:52-61 (Exhibit 2);
- 3. Brosch N. et al. (2000) Characterization and Role in Experimental Systemic Lupus Erythematosus of T-cell Lines Specific to Peptides Based on Complementarity-Determining Region-1 and Complementarity-Determining Region-3 of a Pathogenic Anti-DNA Monoclonal Antibody. Immunology 99:257-264 (Exhibit 3);
- 4. Naparstek, Y. et al. (1989) Sequential Anti-Idiotypes
 Define Reciprocal Idiotopes on the Same Anti-DNA Antibody.

 Clinical Immunology and Immunopathology, 50:S106-S116

 (Exhibit 4);
- 5. Paemen, L. et al. (1994) Evaluation of gelatinases and IL-6 in the cerebrospinal fluid of patients with optic neuritis, multiple sclerosis and other inflammatory neurological diseases. Eur. J. Neurol., 1:55-63 (Exhibit 5);
- 6. Tsokos G.C. et al. (1999) Immune Cell Signaling Defects in Lupus: Activation, Anergy and Death. Immunology Today (Exhibit 6); and
- 7. Waisman, A. et al. (1993) The role of the 16/6 idiotype network in the induction and manifestations of systemic lupus erythematosus. Int. Immunol., 5:1293-300 (Exhibit 7).

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Applicants request that the Examiner review the references and make them of record in the subject application.

If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

No fee is deemed necessary in connection with the filing of this Statement. However, if fee Information Disclosure any required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,

hereby certify this that correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

John P. hite Reg. No. 28,678

Reg. No. 39,992

Gary J. Gershik

John P. White

Registration No. 28,678

Gary J. Gershik

Registration No. 39,992

Attorneys for Applicants

Cooper & Dunham LLP

1185 Avenue of the Americas

New York, New York 10036

(212) 278-0400

Page 1 of 1 Serial No. U.S. Department of Commerce Atty. Docket No. 68811-A/JPW/GJG/NDP 10/758,397 **Patent and Trademark Office** Applicants: Sharon Cohen-Vered et al. FORMATION DISCLOSURE CITATION Filing Date Group (Use several sheets if necessary) January 14, 2004 **U.S. PATENT DOCUMENTS** Subclass Filing Date Class Date Examiner Document Number Name if Appropriate Initial FOREIGN PATENT DOCUMENTS Translation Subclass Document Number Date Country Class Yes WO 9 6 6/24/99 PCT: OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) Brosch N. et al. (2000) A Peptide Based on the Sequence of the CDR3 of a Murine Anti-DNA mAb is a Better Modulator of Experimental SLE than its Single Amino Acid-Substituted Analogs. Cellular Immunology, 205:52-61; Brosch N. et al. (2000) Characterization and Role in Experimental Systemic Lupus Erythematosus of T-cell Lines Specific to Peptides Based on Complementarity-Determining Region-1 and Complementarity-Determining Region-3 of a Pathogenic Anti-DNA Monoclonal Antibody. Immunology 99:257-264; Naparstek, Y. et al. (1989) Sequential Anti-Idiotypes Define Reciprocal Idiotopes on the Same Anti-DNA Antibody. Clinical Immunology and Immunopathology, 50:S106-S116; Paemen, L. et al. (1994) Evaluation of gelatinases and IL-6 in the cerebrospinal fluid of patients with optic neuritis, multiple sclerosis and other inflammatory neurological diseases. Eur. J. Neurol. 1:55-63; Tsokos G.C. et al. (1999) Immune Cell Signaling Defects in Lupus: Activation, Anergy and Death. Immunology Today; and Waisman, A. et al. (1993) The role of the 16/6 idiotype network in the induction and manifestations of systemic lupus erythematosus. Int. Immunol., 5:1293-300.

EXAMINER

DATE CONSIDERED

*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609: Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Exhibit A